IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

ALMA PALACIOS,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	**Case No.:** 5:22-cv-00454
	)	
JOHNSON & JOHNSON and ETHICON, INC.,	)	
	)	
	)	**JURY TRIAL DEMANDED**
	)	
Defendants.	)	

COMPLAINT

Plaintiff Alma Palacios ("Plaintiff"), by and through her attorneys of record, and, for her claims against Defendants Johnson & Johnson and Ethicon, Inc. ("Defendants") states and alleges as follows:

JURISIDICTION AND VENUE

1. This Court has diversity subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332: "The district courts shall have original jurisdiction of all civil actions where the matter in controversy exceeds the sum or value of $75,000.00, exclusive of interest and costs, and is between (1) citizens of different states."

2. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(2) in that a substantial part of the events or omissions giving rise to the claims occurred in this District, the Plaintiff resides in this District, and the Defendants are licensed to do business in this state.

3. This Court has personal jurisdiction over this action and each of the Plaintiff's claims for relief because Defendants have sufficient contacts with the State of Texas such that they

are subject to personal jurisdiction within Texas in that they purposefully availed themselves of the privilege of conducting activities in this forum by placing their goods into the stream of commerce in the United States and this state in particular.

PARTIES

4. Plaintiff is, and at all times relevant was, a resident and citizen of the state of Texas and resides and is domiciled in Bexar County, Texas. Plaintiff was implanted in San Antonio, Texas with one or more defective devices designed, manufactured, packaged, labeled, marketed, sold and distributed by the Defendants in Texas, as more fully set forth below.

5. Defendants Johnson & Johnson ("J&J") is a corporation organized and existing under the laws of New Jersey, maintaining its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. J&J organizes its subsidiary businesses into individual Business Units to coordinate the development, manufacture, testing, marketing promotion, training, distribution and sale of its' pelvic floor repair products. Within J&J there are three sectors, medical devices and diagnostics, pharmaceutical, and consumer. Within the medical devices and diagnostic sector are "Business Units" including the "Ethicon Franchise." The Ethicon Franchise was charged by J&J with the design, development, promotion, marketing, testing, training, distribution and sale of the pelvic floor repair products at issue in this case. The companies which comprise the Ethicon Franchise are thus controlled by J&J and include, but are not limited to, Ethicon Inc., Ethicon LLC, Ethicon LTD. J&J is a citizen of New Jersey.

6. Defendant Ethicon, Inc., is a wholly owned subsidiary of Defendant J&J and located in Somerville, New Jersey. Ethicon, Inc. is a corporation organized and existing under New Jersey law, maintaining its principal place of business at 555 US Route 22, Somerville, New Jersey 08876. Ethicon, Inc. is a citizen of New Jersey.

7. J&J and Ethicon, Inc. are collectively referred to herein as "Ethicon" or "Defendants."

8. All acts and omissions of Defendants, as described herein, were done by their agents, servants, employees, and/or owners acting in the course and scope of their respective agencies, services, employments, and/or ownership.

FACTUAL BACKGROUND

A. Stress Urinary Incontinence and Pelvic Organ Prolapse

9. Defendants promote their pelvic mesh products as devices intended to treat stress urinary incontinence and /or pelvic organ prolapse.

10. Stress urinary incontinence ("SUI") is the involuntary loss of urine during movement that puts pressure on the bladder, such as laughing, coughing, sneezing, or aerobic or strenuous exercise. Although incontinence is suffered by both men and women, it is more common in women and can be caused by menopause or by physical changes that occur in the body during pregnancy or childbirth.

11. Childbirth, for example, can injure the pelvic floor muscles and ligaments that help support a woman's bladder. If these structures weaken, the bladder can move downward, pushing slightly out of the bottom of the pelvis toward the vagina. The movement of the bladder, or other pelvic organs, such as the urethra, cervix or rectum, is known as pelvic organ prolapse ('POP"). A prolapsed bladder can prevent the muscles that ordinarily force the urethra shut from squeezing as tightly as they should, resulting in an involuntary loss of urine.

12. Both SUI and POP are, in many cases, treatable. A woman who elects to have SUI or POP surgically treated has several options. SUI, for example, can be corrected through abdominal surgery using sutures to attach the urethra to a ligament in the pelvis (known as the

"Burch procedure"). SUI also can be surgically addressed using synthetic materials such as suprapubic mid-urethral "slings" placed under the urethra to provide support. Similarly, POP can be corrected through traditional procedures via abdominal or transvaginal surgery. POP also can be surgically addressed using biologic, composite, or synthetic materials.

13. Surgical mesh products have been used to repair abdominal hernias since the 1950s. In the 1970s, gynecologists began using surgical mesh products that were designed for abdominal hernia repair to surgically repair POPs. In the 1990s, gynecologists began using this surgical mesh for the surgical treatment of SUI.

14. Manufacturers (such as Defendants) also began to modify the mesh used in hernia repair to be used as "pelvic mesh products" specifically intended to correct SUI and POP. Defendants manufactured and sold pelvic mesh products, as well as pelvic mesh "kits," which can include the surgical mesh and also tissue fixation anchors and insertion tools as recently as 2019.

15. The pelvic mesh products manufactured by Defendants are considered Class II medical devices.

16. Unlike Class III medical devices, such as an artificial heart or an Automated External Defibrillator, Class II devices do not require "approval" by the Food and Drug Administration ("FDA"). Whereas Class III devices cannot be sold until the manufacturer demonstrates to the FDA, through adequate and well-controlled clinical trials, that the proposed device is safe and effective, there is no such requirement for Class II devices.

17. Under the FDA's "Substantial Equivalence" process under Section 510(k) of the Food, Drug and Cosmetic Act, a manufacturer must provide a premarket notification that allows the FDA to determine whether a medical device is substantially equivalent to a "predicate device." A predicate device is one that the FDA has placed into one of three categories and "cleared" for

marketing.

18. The "premarket notification" process -- for Class II devices -- is not focused on whether the device is safe and effective, but rather is concerned with whether the proposed device is substantially equivalent to an existing predicate device that was already cleared for marketing by the FDA.

19. At all times material to this action, Defendants designed, tested, patented, manufactured, packaged, labeled, marketed, sold, and distributed a line of pelvic mesh products intended to treat POP and SUI. Each of these products was cleared for sale in the United States after the Defendants made assertions to the FDA of "Substantial Equivalence" under Section 510(k). This clearance process does not require the applicant to prove safety or efficacy.

20. One of the pelvic mesh products that Defendants designed, tested, patented, manufactured, packaged, labeled, promoted, marketed, sold, and distributed was the Gynecare TVT Secur ("TVT," "Defendants' Pelvic Mesh Product" and "Product"), which was intended to treat SUI.

21. Defendants were aware, or should have been aware, of the dangers inherent in the Product, notwithstanding the fact that the Product was "cleared" for sale by the FDA.

B. The Plaintiff's Experience with the Product

22. On or about February 17, 2009, Plaintiff was implanted with the Product as treatment for stress urinary incontinence. The Product was implanted by Dr. Ernesto Hernandez at Christus Santa Rosa Healthcare, Santa Rosa City Centre in Santa Rosa, Texas in compliance with the applicable medical standard of care.

23. The Product was implanted for its intended use.

24. Plaintiff's surgery was performed without intraoperative complications.

25. On or about May 18, 2020, Plaintiff was diagnosed with erosion of the Product.

26. Plaintiff underwent removal of the Product on or about June 13, 2020 by Dr. Alexandriah Alas in San Antonio, Texas.

27. As a result of having the Product implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, permanent and substantial physical deformity, has undergone and likely will undergo corrective surgery or surgeries, and has suffered financial or economic loss, including, but not limited to obligations for medical services and expenses.

28. Plaintiff, in the exercise of due diligence, could not reasonably have discovered the cause of her injuries, including, but not limited to, the defective design and/or manufacturing of the Product implanted inside of her, until recently.

CAUSES OF ACTION

COUNT I
NEGLIGENCE
(Tex. Civ. Prac. & Rem. Code § 82-001 *et seq.*)

29. All paragraphs of this Complaint are hereby incorporated by reference as if fully set forth herein.

30. At all times material hereto, Defendants had a duty to Plaintiff and to other foreseeable users of the Product to exercise reasonable care in the design, manufacture, testing, inspection, processing, advertising, marketing, labeling, assembling, packaging, distribution, detailing, promotion and sale of the Product.

31. Defendants had a further duty to provide adequate and sufficient instructions concerning the proper use of the Product, as well as warnings of the risks, complications and dangers associated with using the Product, to Plaintiff and to other foreseeable users of the Product.

32. Defendants breached their duties to Plaintiff when they failed to exercise reasonable care in the design, manufacture, testing, inspection, processing, advertising, marketing, testing, labeling, assembling, packaging, distribution, detailing, promotion and sale of the Product so as to avoid unreasonable risk of harm to women in whom the Product was implanted, including Plaintiff.

33. Defendants breached their duty to provide adequate and sufficient instructions concerning the proper use of the Product, as well as warnings of the risks, complications and dangers associated with using the Product, to Plaintiff, her implanting surgeon, and to other foreseeable users of the Product.

34. Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the pelvic mesh products.

35. The Product implanted in Plaintiff was unreasonably dangerous and defective for reasons that include, but are not limited to, the following:

a. The use of polypropylene material in the Product and the immune reaction that results from such material, causing adverse reactions and injuries;

b. The design of the Product to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. Biomechanical issues with the design of the Product, including, but not limited to, the propensity of the Product to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. The use and design of arms and anchors in the Product, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. The propensity of the Product for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. The inelasticity of the Product, causing it to be improperly mated to the delicate and sensitive areas of the pelvis where it is implanted, and causing pain upon normal

daily activities that involve movement in the pelvis (e.g., intercourse, defecation);

g. The propensity of the Product for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanted according to the manufacturers' instructions.

i. The Product degrades over time, causes chronic foreign body reactions, fibrotic bridging, mesh contracture / shrinkage, fraying, deformation, roping, rolling and curling of the mesh;

j. Lacked adequate studies to establish safety and effectiveness for permanent human implantation to treat SUI;

k. Directions For Use ("DFU") Defendants provided with all Products do not fully disclose or adequately warn about the Product's known or knowable risks, adverse reactions, and characteristics;

l. The use of polypropylene material in the Product and the failure to provide adequate DFU and training;

m. Defendants failed to design and establish a safe, effective procedure for removal of their pelvic mesh products; therefore, in the event of a failure, injury, or complication it is impossible to easily and safely remove; and

n. The pore size and stiffness of the device was unsafe and resulted in unnecessary complications to women and created an unacceptable risk of chronic pain and the mesh ripping through vaginal tissue.

36. Defendants also breached their duty to adequately and sufficiently warn Plaintiff and her healthcare providers and other foreseeable users of the Product of the Product's propensity to erode, the rate and manner of mesh erosion, the risk of chronic infections resulting from implantation of the Product, the risk of vaginal scarring as a result of implantation of the medical devices, the risk of recurrent severe pelvic pain and other pain resulting from the implantation of the Product, the need for corrective or revisionary surgery to adjust or repair the Product, or the overall severity of complications that could arise as a result of implantation of the Product.

37. Defendants' pelvic mesh products incorporate a monofilament polypropylene mesh intended for the treatment of POP and/or SUI. Despite claims that this material is inert, the emerging scientific evidence suggests that this material is biologically incompatible with human tissue and promotes an immune response in a large subset of the population receiving Defendants' pelvic mesh products containing this material. This immune response promotes degradation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh. Moreover, the mesh migrates within the surrounding tissues causing irreparable damage to the tissue including nerve endings residing within the tissues. Damaged nerve endings do not regenerate and lead to debilitating neuromas suffered by patients.

38. Defendants made claims and representations in documents they submitted to the FDA, in their reports to the public and to healthcare professionals, and in advertisements that the Product did not present serious health risks.

39. These and other representations made by Defendants were false when made and/or were made with the pretense of actual knowledge, when such knowledge did not actually exist, and were made recklessly and without regard to the true facts.

40. These and other representations made by Defendants were made with the intention of deceiving Plaintiff, Plaintiff's healthcare professionals, and other members of the healthcare community and were made in order to induce Plaintiff and her healthcare professionals to rely on misrepresentations and caused Plaintiff to purchase, rely, use, and request the Product and her healthcare professionals to dispense, recommend, or prescribe the Product.

41. Defendants' pelvic mesh products have been and continue to be marketed to the medical community and to patients as safe, effective, reliable, medical devices implanted by safe and effective minimally invasive surgical techniques for the treatment of medical conditions,

primarily POP or SUI, and as safer and more effective as compared to the traditional products and procedures for treatment and other competing pelvic mesh products.

42. The Defendants have marketed and sold their pelvic mesh products to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, aggressive marketing to health care providers at medical conferences, hospitals, and private offices and include the provision of valuable cash and non-cash benefits to health care providers. Also utilized are documents, brochures, and websites offering exaggerated and misleading expectations as to the safety and utility of the products.

43. Contrary to the Defendants' representations and marketing to the medical community and to the patients themselves, the Defendants' pelvic mesh products have high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff, making them defective under the law. The Defendants consistently have underreported and withheld information about the propensity of their pelvic mesh products to fail and cause injury and complications, have misrepresented the efficacy and safety of their products, and, through various means and media, have actively and intentionally been misleading the FDA, the medical community, patients, and the public at large.

44. Defendants knew and had reason to know that the Product could and would cause severe and grievous personal injury to its users and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

45. Defendants knew or had reason to know that Plaintiff and her physicians and other healthcare providers had no way to determine the truth behind Defendants' concealment and

omissions and that these included material omissions of facts surrounding the use of the Product, as described in detail above.

46. In reliance upon these false representations, Plaintiff was induced to and did use the Product, thereby sustaining severe and permanent personal injuries and damages.

47. Had Plaintiff or her treating physician known of the unreasonably dangerous risks associated with the Product at the time of her implant surgery, such knowledge would have affected the treating physician's use of the device and Plaintiff would not have consented to the implantation of the device.

48. As a direct and proximate result of Defendants' breaches of duty, as described above, Plaintiff has suffered serious and permanent physical and mental injuries and pain and suffering; has undergone medical treatment and likely will undergo further medical treatment and procedures; and has suffered financial and economic loss, including, but not limited to, medical expenses, lost income, out of pocket expenses, and other damages.

49. As a direct, proximate, and foreseeable result of Defendants' negligence, Plaintiff has been damaged in an amount to be determined at trial.

COUNT II
STRICT LIABILITY – DESIGN DEFECT
(Tex. Civ. Prac. & Rem. § 82-001 *et seq.*)

50. All paragraphs of this Complaint are hereby incorporated by reference as if fully set forth herein.

51. The Product implanted in Plaintiff was not merchantable and reasonably safe for its intended use and was defective as described herein with respect to its design. The Product's design defects include, but are not limited to:

a. The use of polypropylene material in the Product and the immune reaction that results from such material, causing adverse reactions and injuries;

b. The design of the Product to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. Biomechanical issues with the design of the Product, including, but not limited to, the propensity of the Product to contract or shrink inside the body, that in turn causes surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. The use and design of arms and anchors in the Product, which, when placed in women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. The propensity of the Product to "creep" or to gradually elongate and deform when subject to prolonged tension inside the body;

f. The inelasticity of the Product, causing it to be improperly mated to the delicate and sensitive areas of the pelvis where it is implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);

g. The propensity of the Product for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction and results in continuing injury over time;

h. The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanted according to the manufacturer's instructions;

i. The use of polypropylene material in the Product and the failure to provide adequate DFU and training; and

j. The pore size and stiffness of the device was unsafe and resulted in unnecessary complications to women and created an unacceptable risk of chronic pain and the mesh ripping through vaginal tissue.

52. As a result of the design defects set forth herein, the risk of harm in the Product's design outweighed the utility of their design.

53. Feasible, suitable and safer alternative designs, as well as feasible, suitable and safer alternative procedures and instruments for implantation, have existed at all times relevant as compared to the pelvic mesh products. These feasible, suitable and safer alternative designs and procedures would have prevented or minimized Plaintiff's injuries.

54. The Product implanted into Plaintiff was in the same or substantially similar condition as it was when it left the possession of Defendants and in the condition directed by and expected by the Defendants.

55. Plaintiff and her physicians foreseeably used and implanted the Product and did not misuse or alter the Product in an unforeseeable manner.

56. The medical and scientific literature studying the effects of polypropylene pelvic mesh, like Defendants' pelvic mesh products, have examined injuries, conditions, and complications, such as those suffered by Plaintiff, and determined that they are, in fact, causally related to the mesh itself and do not often implicate errors related to the implantation of the devices.

57. As a direct and proximate result of the Product's aforementioned defects as described herein, Plaintiff has suffered serious and permanent physical and mental injuries and pain and suffering; has undergone medical treatment and likely will undergo further medical treatment and procedures; and has suffered financial and economic loss, including, but not limited to, medical expenses, lost income, out of pocket expenses, and other damages.

58. Defendants are liable to Plaintiff for designing, marketing, labeling, packaging, and selling the defective product.

COUNT III
STRICT LIABILITY – MANUFACTURING DEFECT
(Tex. Civ. Prac. & Rem. § 82-001 *et seq.*)

59. All paragraphs of this Complaint are hereby incorporated by reference as if fully set forth herein.

60. The Product implanted in Plaintiff was not reasonably safe for its intended and foreseeable use and was defective as described herein as a matter of law with respect to its manufacture in that it deviated materially from Defendants' design and manufacturing

specifications in such a manner as to pose unreasonable risks of serious bodily harm to Plaintiff.

61. At all relevant times Defendants were the manufacturer of the Product.

62. Defendants designed, manufactured, prepared, assembled, marketed, labeled, distributed and sold the Product.

63. The Defendants designed the Product as a permanent implant for long term use within the human body.

64. However, due to the manufacturing defect of the mesh system, the device was not safe or effective for long term use.

65. The manufacturing of the Product was defective due to, among other things, the use of non-medical grade material and inadequate specifications that were not adhered to in the manufacturing of Plaintiff's devices.

66. The Defendants' Product is not compatible with human tissue and promotes an immune response in a large subset of the population.

67. The Defendants' pelvic mesh products have high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff, making them defective under the law.

68. The Product's defects, as described herein, made the Product more dangerous than it would have been had the Product been manufactured properly and as specified.

69. The Product's defects, as described herein, existed at the time the Product left Defendants' control.

70. The Product implanted into Plaintiff was in the same or substantially similar condition as it was when it left the possession of Defendants and in the condition directed by and

expected by the Defendants.

71. The Product was at all times utilized and implanted in a manner foreseeable to the Defendants, as Defendants generated the DFUs, created the procedure for implanting the devices, and trained the implanting physicians.

72. As a direct and proximate result of the Product's aforementioned defects as described herein, Plaintiff has suffered serious and permanent physical and mental injuries and pain and suffering; has undergone medical treatment and likely will undergo further medical treatment and procedures; and has suffered financial and economic loss, including, but not limited to, medical expenses, lost income, out of pocket expenses, and other damages.

73. Defendants are liable to Plaintiff for manufacturing and selling the defective Product.

COUNT IV
STRICT LIABILITY – FAILURE TO WARN
(Tex. Civ. Prac. & Rem. § 82-001 *et seq.*)

74. All paragraphs of this Complaint are hereby incorporated by reference as if fully set forth herein.

75. Defendants had a duty to give an adequate warning of known or reasonably foreseeable dangers, risks and complications arising from the use of the Product. Defendants owed this duty to warn to all persons whom Defendants should have reasonably foreseen may use or be affected by the Product, including, but not limited to, Plaintiff, Plaintiff's healthcare providers, and the FDA.

76. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public, Plaintiff, Plaintiff's healthcare providers, and the FDA.

77. The Product implanted in Plaintiff was not reasonably safe for its intended uses and was defective as described herein as a matter of law due to its lack of adequate, appropriate and necessary warnings. Specifically, Defendants did not provide sufficient or adequate warnings regarding, among other subjects:

a. The Product's propensities to contract, retract, and/or shrink inside the body;

b. The Product's propensities for degradation, fragmentation, disintegration and/or creep;

c. The Product's inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. The rate and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Product;

f. The risk of chronic infections resulting from the Product;

g. The risk of permanent vaginal or pelvic scarring as a result of the Product;

h. The risk of recurrent, intractable pelvic pain and other pain resulting from the Product;

i. The need for corrective or revision surgery to adjust or remove the Product;

j. The severity of complications that could arise as a result of implantation of the Product;

k. Treatment of SUI with the Product is no more effective than feasible available alternatives;

l. Treatment of SUI with the Product exposes patients to greater risk than feasible available alternatives;

m. Treatment of SUI with the Product makes future surgical repair more difficult than feasible available alternatives;

n. Use of the Product puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

o. Removal of the Product due to complications may involve multiple surgeries and may significantly impair the patient's quality of life;

p. Complete removal of the Product may not be possible and may not result in complete resolution of the complications, including pain; and

q. The nature, magnitude, and frequency of complications that could arise as a result of implantation of the Product; and

r. The material was never intended to be used in a medical device permanently implanted in the body and the material was non-medical grade.

78. Defendants acted unreasonably in failing to undertake their duties to properly know the qualities of their products and, in representations to Plaintiff and/or to Plaintiff's healthcare providers, concealed and intentionally omitted the following material information:

a. That the Product was not as safe as other products and procedures available to treat incontinence and/or prolapse;

b. That the risk of adverse events with the Product was higher than with other products and procedures available to treat incontinence and/or prolapse;

c. That the risk of adverse events with the Product was known by Defendants and was not adequately tested;

d. That the limited clinical testing revealed the Product had a higher risk of adverse effects in addition to and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

e. That Defendants failed to follow up on the adverse results from clinical studies and buried and/or misrepresented those findings;

f. That Defendants were aware of dangers in its pelvic mesh products, including the pelvic mesh systems, in addition to and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

g. That the pelvic mesh systems were dangerous and caused adverse side effects, including, but not limited to, higher incidence of erosion and failure at a much more significant rate than other products and procedures available to treat incontinence and/or prolapse;

h. That patients frequently would need revisionary surgery due to changes in the structure of the Product that would cause it to be become loose or shift position within the body;

i. That patients needed to be monitored more regularly than usual while using the Product and, in the event the Product needed to be removed, that the procedure to remove the Product had a very high failure rate and/or needed to be performed repeatedly;

j. That material Defendants were using carried a specific safety warning to never be used as a permanent implant in the human body;

k. That Defendants rushed the Product to market against the concerns of consultants and employees;

l. That Defendants were aware of safety issues with design of the Product and the pain it caused to patients;

m. That Defendants were aware the Product was not as safe or efficacious as other alternatives;

n. That Defendants' internal risk assessments concluded there was lack of data to support the safety and efficacy of the Product; and

o. That Defendants received complaints about the design of Product, including from their own consultants, only to conceal them and not make changes to the design.

79. Defendants were under a duty to disclose to Plaintiff and her physicians the defective nature of the Product, including, but not limited to, the heightened risks of erosion, failure, and permanent injury.

80. Defendants misrepresented to the medical and healthcare community, Plaintiff, the FDA, and the public at large that the pelvic mesh products had been tested and were found to be safe and effective for the purposes of treating SUI and POP.

81. These representations were made by Defendants with the intent of inducing Plaintiff, the medical community, and the public to recommend, prescribe, dispense, and purchase the pelvic mesh products for use as a means of treatment for SUI and/or POP, all of which evinced an indifference to the health, safety, and welfare of Plaintiff.

82. Defendants had sole access to material facts concerning the defective nature of the Product and its propensity to cause serious and dangerous side effects and, hence, cause dangerous injuries and damage to women who used the Product, including Plaintiff.

83. At the time these representations were made by Defendants and at the time Plaintiff

used the Product, she and her implanting surgeon were unaware of the falsehood of these representations, and reasonably believed them to be true.

84. Defendants' concealment and omissions of material facts concerning the safety of their pelvic mesh products were made to cause Plaintiff's physicians and healthcare providers to purchase, prescribe, and/or dispense the Product and/or to mislead Plaintiff into reliance and cause Plaintiff to use the Product.

85. Defendants provided incomplete, insufficient, and misleading training and information to physicians in order to increase the number of physicians utilizing the pelvic mesh products and, thus, increase the sales of the pelvic mesh products, leading to the dissemination of inadequate and misleading information to patients, including Plaintiff.

86. Defendants intentionally made material misrepresentations to the medical community and public, including Plaintiff, regarding the safety of the Product, specifically that it did not have dangerous and/or serious adverse health safety concerns and that it was as safe as other means of treating SUI and/or POP.

87. Defendants intentionally failed to inform the public, including Plaintiff and her implanting surgeon, of the high failure rate, erosion, the difficulty of removing the Product, and the risk of permanent injury.

88. Instead, Defendants chose to over-promote the safety, efficacy, and benefits of the Product.

89. Had Plaintiff known the true facts about the dangers and serious health and/or safety risks of the Product, she would not have purchased, used, consented to, or relied on the Product.

90. As a direct and proximate result of the Product's aforementioned defects as described herein, Plaintiff has suffered serious and permanent physical and mental injuries and pain

and suffering; has undergone medical treatment and likely will undergo further medical treatment and procedures; and has suffered financial and economic loss, including, but not limited to, medical expenses, lost income, out of pocket expenses, and other damages.

91. Defendants are liable to Plaintiff for its failure to provide adequate and sufficient warnings to Plaintiff and to foreseeable users of the defective Product.

COUNT V
BREACH OF WARRANTIES
(Tex. Civ. Prac. & Rem. § 82-001 *et seq.*)

92. All paragraphs of this Complaint are hereby incorporated by reference as if fully set forth herein.

93. At all times material hereto, the Product was widely sold, distributed, marketed, promoted, and advertised by Defendants as devices to treat SUI for women, including Plaintiff.

94. Defendants marketed, promoted, advertised, sold and distributed the Product in the State of Texas and into the stream of commerce knowing that it would enter the State of Texas and be used therein.

95. When Defendants placed the Product into the stream of commerce, they knew of the uses for which the device was intended (to treat POP and/or SUI) and expressly and impliedly warranted the Product to be of merchantable quality and to be safe and effective and fit for such uses.

96. Defendants made numerous representations about the quality, safety, and effectiveness of the device, which formed warranties.

97. At the time of making the warranties, Defendants knew or should have known that, in fact, said representation and warranties were false, misleading, and untrue in that the Product was not safe and fit for its intended use and, in fact, produces serious injuries to the user, including

Plaintiff.

98. Plaintiff and her implanting surgeon reasonably relied upon the expertise, skill, judgment and knowledge of Defendants and on the express and/or implied warranties that the Product was of merchantable quality and fit for use to treat SUI.

99. The Product did not conform to Defendants' representations and was not of merchantable quality and was not safe or fit for its intended use because the Product was, and is, unreasonably dangerous and unfit for the ordinary and expected purposes for which it is used in that it caused injury to Plaintiff and others far beyond any acceptable or warned of risk or complication.

100. As a direct and proximate result of Defendants' breach of the aforementioned express and implied warranties, Plaintiff has suffered serious and permanent physical and mental injuries and pain and suffering; has undergone medical treatment and likely will undergo further medical treatment and procedures; and has suffered financial and economic loss, including, but not limited to, medical expenses, lost income, out of pocket expenses, and other damages.

COUNT VI
GROSS NEGLIGENCE

101. All paragraphs of this Complaint are hereby incorporated by reference as if fully set forth herein.

102. In committing the acts and/or omissions set forth herein that directly and proximately caused Plaintiff's injuries, as set forth herein, Defendants breached their duty to Plaintiff and demonstrated a conscious, reckless, willful, and wanton indifference to and disregard of the consequences of its actions and/or omissions.

103. Defendants have known and continue to know that some of the predicate products for their pelvic mesh products had high failure and complication rates, resulting in the recall of

some of these predicate devices; that there were and are differences between Defendants' pelvic mesh products and some or all of the predicate products, rendering them unsuitable for designation as predicate products; that significant differences exist and existed between the pelvic mesh products and their predecessor and predicate products, such that the disclosures to the FDA were and are incomplete and misleading; and that the pelvic mesh products were and are causing numerous patients severe injuries and complications. The Defendants suppressed this information and failed to accurately and completely disseminate or share this and other critical information with the FDA, healthcare providers, or the patients, including Plaintiff.

104. As a result, the Defendants actively and intentionally misled and continue to mislead the public, including the medical community, health care providers, and patients, into believing that the pelvic mesh products and the procedures for their implantation were and are safe and effective. This led to the prescription for and implantation of the Product into Plaintiff.

105. The injuries, conditions, and complications suffered by women who have been implanted with Defendants' pelvic mesh products include, without limitation: mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia, blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, chronic pelvic pain, urinary and fecal incontinence, the recurrent prolapse of organs, and, in many cases, the women have been forced to undergo intensive medical treatment including, but not limited to, operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

106. Again, Defendants had sole access to material facts concerning the defective nature

of the Product and its propensity to cause serious and dangerous side effects and, hence, cause dangerous injuries and damage to women who used the Product, including Plaintiff.

107. Defendants were grossly negligent by showing a complete indifference for the safety and health of Plaintiff and others similarly situated in negligently designing, packaging, labeling, marketing, advertising, promoting, distributing, and selling defective and unreasonably dangerous products and in negligently failing to warn Plaintiff of the significant risks and complications associated with their devices, as set forth above.

108. In light of the knowledge Defendants had concerning the risks and complications associated with their devices, as set forth above, Defendants continued to show an utter disregard and complete indifference for the safety of Plaintiff by failing to provide adequate warnings concerning the risks and complications associated with their devices, making material misrepresentations and placing profits from sales of its devices over the safety of patients receiving their devices, including Plaintiff.

109. The wrongs done by Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff for which the law will not allow, and for which Plaintiff seeks punitive and/or exemplary damages, in that Defendants' conduct, including the failure to comply with applicable industry standards, was specifically intended to cause substantial injury to Plaintiff; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, including Plaintiff, and Defendant actually was subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others, including Plaintiff; or included a material representation that was false, with Defendants knowing that it was false or with reckless disregard

as to its truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff and her implanting surgeon.

110. As a direct and proximate result of Defendants' gross negligence, Plaintiff has suffered serious and permanent physical and mental injuries and pain and suffering; has undergone medical treatment and likely will undergo further medical treatment and procedures; and has suffered financial and economic loss, including, but not limited to, medical expenses, lost income, out of pocket expenses, and other damages.

COUNT VII
PUNITIVE DAMAGES

111. All paragraphs of this Complaint are hereby incorporated by reference as if fully set forth herein.

112. Defendants sold the Product to the healthcare providers of Plaintiff in the State of Texas and throughout the United States without doing adequate testing to ensure that the Product was reasonably safe for implantation in the female pelvic area.

113. Defendants sold the Product to Plaintiff's health care providers and other health care providers in the State of Texas and throughout the United States in spite of its knowledge that the Product can shrink, disintegrate and/or degrade inside the body and cause the other problems heretofore set forth in this Complaint, thereby causing severe and debilitating injuries suffered by Plaintiff and numerous other women.

114. Defendants ignored reports from patients and healthcare providers throughout the United States and elsewhere of the Product's failures to perform as intended, which led to the severe and debilitating injuries suffered by Plaintiff and numerous other women. Rather than doing adequate testing to determine the cause of these injuries or to rule out the Product's designs or the processes by which the Product is manufactured as the cause of these injuries, Defendants chose

instead to continue to market and sell the Product as safe and effective.

115. Defendants withheld material information from the FDA, the medical community and the public in general, including Plaintiff, regarding the safety and efficacy of the Product.

116. Defendants knew and recklessly disregarded the fact that the Product caused debilitating and potentially life altering complications with greater frequency than feasible alternative methods and/or products used to treat POP and SUI.

117. Defendants misstated and misrepresented data and continues to misrepresent data so as to minimize the perceived risk of injuries caused by the Product.

118. Notwithstanding the foregoing, Defendants continued to aggressively market the Product to consumers, without disclosing the true risks associated with the Product.

119. Defendants knew of the Product's defective and unreasonably dangerous nature, but continued to mislead physicians and patients and to manufacture, market, distribute, and sell the Product so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff.

120. Defendants continue to conceal and/or fail to disclose to the public, including Plaintiff, the serious complications associated with the use of the Product.

121. Defendants' conduct as described herein shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care that raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that the Court enter judgment in her favor against Defendants for actual, compensatory and punitive damages, plus attorneys' fees and expenses, costs, interest, and such other and further relief as the Court may deem just and proper.

DESIGNATION OF PLACE OF TRIAL

Plaintiff hereby designates San Antonio, Texas as the location for trial in this matter.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury in this action.

Dated: May 9, 2022

Respectfully submitted,

THE POTTS LAW FIRM, LLP

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